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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,223	04/23/2001	Jan Topholm	Q64069	4742

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EXAMINER

ENSEY, BRIAN

ART UNIT	PAPER NUMBER
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2643

13

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,223

Applicant(s)

TOPHOLM, JAN

Examiner

Brian Ensey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39 and 40 is/are allowed.
- 6) ☒ Claim(s) 17-38 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitt et al., U.S. 5,889,874 in view of Widemar et al., U.S. 6,533,062.

Regarding claim 21, Schmitt discloses a hearing aid (1) for insertion in the auditory canal, comprising a hearing aid housing manufactured according to the users auditory canal so that a first part (2) provides a surface adapted to match the shape of the auditory canal of the user, a second part provides a surface adapted to face the surroundings, a battery opening (7) and a socket engagement (18) means, and a third part (3) provides an end wall and an acoustic output opening (See Fig. 2 and col.2, line 30 through col. 3, line 16). Schmitt does not expressly disclose the housing is a digital model of the users auditory canal. However, Schmitt teaches the shell is individually fabricated (customized) with an ear impression and Widemar teaches a process for manufacturing, custom-moulded ear inserts using three-dimensional image data from a users auditory canal to provide digitized data and modeling. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the digitized data of Widemar to produce the custom ear moulded shell of Schmitt for an accurate and comfortable hearing aid shell.

2. Claims 17, 19, 20, 26, 41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voroba et al., U.S. 4,870,688 in view of Widemar.

Regarding claim 17, Voroba discloses a hearing aid for insertion in the auditory canal, comprising a shell (20,30,40) matched to the auditory canal of a user, and a face plate

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(100), so as to have a shell junction contour, shell positioning means, first component engagement means, and an acoustic output opening, said first component engagement means being adapted for receiving and holding a receiver, wherein said face plate is manufactured so as to have a circumference matching said junction contour, face plate positioning means (110,112,114,116), and second component engagement means, and wherein said face plate positioning means is adapted for engaging with said shell positioning means, so as to make said shell and said face plate provide a hearing aid housing (See Fig. 1 and col. 9, lines 29-54).

Voroba does not expressly disclose the shell and face plate are fabricated to a digital model of the users auditory canal. However, Voroba teaches the shell is form fitting and conforms to the patient's own ear and Widemar teaches a process for manufacturing, custom-moulded ear inserts using three-dimensional image data from a users auditory canal to provide digitized data and modeling. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the digitized data of Widemar to produce the custom ear moulded shell of Voroba for an accurate and comfortable hearing aid shell.

Regarding claims 19 and 20, Voroba further discloses said face plate positioning means comprises at least one face plate protrusion at the inner surface of the face plate terminating at the circumference of the face (110) at a distance from the circumference that is substantially equal to the thickness of the shell at said junction contour, and wherein the shell positioning means comprise the shell at the junction contour and the protrusions at the junction contour extend inwardly towards the interior of the shell (52) for reception and holding corresponding face plate protrusions (See Fig. 1 and col. 9, lines 29-54).

Regarding claim 26, Voroba further discloses the shell has an integrated ventilation channel (130,132) (See Fig. 4 and col. 10, line 65 to col. 11, line 11)

Regarding claim 41, Voroba discloses a hearing aid as claimed. Voroba does not expressly disclose an inherent identification of the produced hearing aid housing. However, Widmer teaches an inherent identification of the produced hearing aid housing (See col. 14, lines 30-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a unique identification of the hearing aid housing to easily maintain accountability between each unique device and its user.

Regarding claim 43, Voroba does not expressly disclose the shell is manufactured utilizing a rapid prototyping technique. However, Widemar teaches a process for manufacturing, custom-moulded ear inserts using three-dimensional image data from a users auditory canal to provide digitized data and modeling. A digitized mold data is inherent in a rapid manufacturing process and it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a rapid prototyping technique to quickly provide a customized hearing device for consumers.

3. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voroba as applied to claim 17 above, and further in view of Juneau et al., U.S. Patent No. 6,228,020.

Regarding claim 18, Voroba discloses a hearing aid as claimed. Voroba further discloses the face plate positioning means comprise at least one face plate protrusion (110,112,114,116) at the inner surface of the face plate, wherein the shell positioning means comprise indentations (50,52) that are adapted to receive and match the at least one face plate protrusion (See Fig. 1 and col. 9, lines 29-54). Voroba does not expressly disclose the face plate is cut along the circumference so that it matches the junction contour when the at least one face plate protrusion is received by the mating indentations of the shell. However, it is well-known in the art to trim the face plate to match the shell and Juneau teaches trimming the faceplate to match the contour

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of the shell when the pieces are placed in their proper orientation (See Fig. 13 and col. 7, lines 43-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to trim the face plate along the circumference so that it matches the junction contour when the at least one face plate protrusion is received by the mating indentations of the shell for a pleasing appearance and a comfortable fit into the ear of the user.

4. Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voroba as applied to claim 17 above, and further in view of Olsen, U.S. Patent No. 6,430,296.

Regarding claim 22, Voroba discloses an electronic module (60), at least one microphone (90), and a receiver (7), and wherein the hearing aid housing is adapted to enclose the electronic module, the faceplate has a battery opening defined therein for a passage of a battery (See Figs. 1 and 2 and col. 7, line 52 to col. 8, line 53). Voroba does not expressly disclose the faceplate has a battery opening defined therein for a passage of a battery and the electronic module. However, Olsen further discloses an electronic module (4), at least one microphone (5), a signal processor (6), and a receiver (7), and wherein the hearing aid housing is adapted to enclose the electronic module, the faceplate has a battery opening defined therein for a passage of a battery and the electronic module (See Fig. 1 and col. 2, lines 10-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to include a passage through the face plate for the electronics module to further modularize the device and improve manufacturability.

Regarding claim 23, Voroba further discloses a second component engagement means comprises grooves, tracks and/or notches (50,110,112) for engagement with a socket engaging means formed on the socket (See Figs. 1 and 2 and col. 9, lines 29-54). Voroba does not expressly disclose the electronic module comprises socket engagement means. However, Olsen

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teaches the electronic module comprises socket engagement means (See Figs. 1-4). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a socket for the electronics module to further modularize the device and improve manufacturability.

Regarding claim 24, Voroba does not expressly disclose the second component engagement means comprises elastically resilient lugs. However, Olsen teaches the second component engagement means comprises elastically resilient lugs (See Figs. 1-4 and abstract).

Regarding claim 25, Voroba does not expressly disclose the lugs are integrated with battery terminals projecting from the electronics module. However, Olsen further discloses the lugs are integrated with battery terminals projecting from the socket (See Fig. 2 and col. 5, lines 17-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to integrate lugs with battery terminals to further modularize the device and improve manufacturability.

5. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vorba as applied to claim 17 above, and further in view of Nessler, U.S. Patent No. 4,879,750.

Regarding claim 28, Voroba discloses a hearing aid as claimed. Voroba does not expressly disclose the shell has a shell ventilation channel opening that is adapted to receive and hold an ear wax guard. However, Nessler teaches the shell has a shell ventilation channel opening that is adapted to receive and hold an ear wax guard (See Figs. 10 and 11 and col. 3, lines 7-10 and col. 4, lines 10-25).

6. Claims 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voroba as applied to claim 17 above, and further in view of Berger, U.S. Patent No. 6,164,409.

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Regarding claims 27 and 30, Voroba discloses a hearing aid as claimed. Voroba does not expressly disclose the shell has an acoustic output opening that is adapted to receive and hold an ear wax guard with a recess in the shell covering an area around the opening and matching a collar of the ear wax guard or matching a collar of a bushing to be inserted in the opening for reception and holding of the ear wax guard. However, the use of wax guards are well known in the art and Berger teaches an acoustic output opening (42) that is adapted to receive and hold an ear wax guard (40) with a recess in the shell (34) covering an area around the opening and matching a collar of the ear wax guard (38) or matching a collar of a bushing to be inserted in the opening for reception and holding of the ear wax guard. It would have been obvious to one of ordinary skill in the art at the time of the invention to include an ear wax guard to prevent contamination of the output duct and attenuation of the output signal.

7. Claims 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voroba as applied to claim 17 above, and further in view of Yoest, U.S. Patent No. 5,970,157.

Regarding claims 27 and 29, Voroba discloses a hearing aid as claimed. Voroba does not expressly disclose the shell has an acoustic output opening that is adapted to receive and hold an ear wax guard with a pipe stub in the shell centered around the opening and extending inwardly in the shell and forming a bushing for insertion of the ear wax guard. However, the use of wax guards are well known in the art and Yoest teaches an acoustic output opening (18,20) that is adapted to receive and hold an ear wax guard (24) with a pipe stub (22) in the shell centered around the opening and extending inwardly in the shell and forming a bushing for insertion of the ear wax guard (See Fig. 3 and col. 4, lines 1-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to include an ear wax guard to prevent contamination of the output duct and attenuation of the output signal.

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8. Claims 31-35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voroba as applied to claim 17 above, and further in view of Yoest, U.S. Patent No. 6,167,141.

Regarding claim 31, Voroba discloses a hearing aid as claimed. Voroba does not expressly disclose a tightening protrusion extending along the surface of the shell providing a tight seal against the auditory canal wall when the shell is inserted in the auditory canal. However, Yoest teaches a tightening protrusion (68a) extending along the surface of the shell providing a tight seal against the auditory canal wall when the shell is inserted in the auditory canal (See Fig. 3 and col. 4, line 41 to col. 5, line 52). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a tightening protrusion for a comfortable acoustic seal in the ear canal.

Regarding claim 32, Voroba does not expressly disclose the tightening protrusion is made of the same material as the shell, and wherein the outer dimensions of the shell are increased to form the tightening protrusion. However, Yoest teaches the tightening protrusion may be formed from any compliant material (See col. 5, lines 48-52). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a tightening protrusion of the same material as the shell to easily and cheaply form a comfortable acoustic seal in the ear canal.

Regarding claim 33, Voroba discloses a hearing aid as claimed. Voroba does not expressly disclose a groove extending along the surface of the shell and encircling the shell, the groove being adapted to seat a tightening ring adapted to constitute a tightening protrusion. However, Yoest teaches a groove (56c) extending along the surface of the shell and encircling the shell the groove being adapted to seat a tightening ring (68a) to be mounted in the produced shell and constituting a tightening protrusion (See Fig. 3 and col. 4, line 41 to col. 5, line 52). It would

have been obvious to one of ordinary skill in the art at the time of the invention to provide a tightening ring for a comfortable acoustic seal in the ear canal.

Regarding claim 34, Voroba discloses a hearing aid as claimed. Voroba does not expressly disclose a groove extending along the surface of the shell for deposition of a material different from the material of the shell in the groove, the deposited material constituting a tightening protrusion. However, Yoest teaches a groove (56c) extending along the surface of the shell for deposition of a material different from the material of the shell in the groove, the deposited material constituting a tightening protrusion (See Fig. 3 and col. 4, line 41 to col. 5, line 52). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a tightening ring for a comfortable acoustic seal in the ear canal.

Regarding claim 35, Voroba does not expressly disclose the position of the tightening protrusion is selected to correspond to the position in the auditory canal at which the dynamic variations of the dimensions of the auditory canal exhibit the least variations caused by user activity. However, Yoest teaches the end of the shell is located near the ear drum and the tightening protrusion would be effective in sealing the user's auditory canal (See col. 5, lines 21-32). It would have been obvious to one of ordinary skill in the art at the time of the invention to position the protrusion at the position of least distortion of the auditory canal to maintain the most effective seal possible.

9. Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voroba as applied to claim 17 above, and further in view of Gore et al., U.S. Patent No. 4,620,605.

Regarding claim 36, Voroba discloses a hearing aid as claimed. Voroba does not expressly disclose the first component means is adapted for vibration absorbing suspension of the receiver. However, the use of vibration absorption suspensions is well known in the art and Gore teaches

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the shell is produced with means for vibration absorbing suspension of the receiver (See Fig. 4 and abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a suspension for receiver mounting a vibration absorption for a clearer sound signal to be supplied to the user.

Regarding claims 37 and 38, Voroba disclose a hearing aid as claimed. Voroba does not expressly disclose the first component engagement means comprises a chamber for receiving and holding the receiver and at least one resilient band fixed around the receiver wherein the resilient band comprises a protrusion for supporting and suspending the receiver in the chamber. However, the use of vibration absorption suspensions is well known in the art and Gore teaches a chamber (Fig. 4) for receiving and holding the receiver, and at least one resilient band (50) fixed around the receiver and the at least one resilient band has at least one protrusion (54) for supporting and suspending the receiver in the chamber. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a suspension for receiver mounting a vibration absorption for a clearer sound signal to be supplied to the user.

Regarding claim 42, Voroba does not expressly disclose the first component engagement means comprises shell protrusions for receiving and holding the receiver, and at least one resilient band fixed around the receiver. However, the use of vibration absorption suspensions is well known in the art and Gore teaches a chamber (Fig. 4) for receiving and holding the receiver, and at least one resilient band (50) fixed around the receiver and the at least one resilient band has at least one protrusion (54) for supporting and suspending the receiver in the chamber. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a shell protrusion for receiver mounting a vibration absorption for a clearer sound signal to be supplied to the user.

Allowable Subject Matter

Claims 39 and 40 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Ensey whose telephone number is 703-305-7363. The examiner can normally be reached on Mon-Fri: 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Kuntz can be reached on 703-305-4708. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any response to this action should be mailed to:

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Or faxed to:

(703) 872-9306, for formal communications intended for entry and for informal or draft communications, please label "PROPOSED" or "DRAFT".

Hand-delivered responses should be brought to Crystal Park II, 2121 Crystal Drive,
Arlington, VA., Sixth Floor (Receptionist).

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BKE

April 14, 2004


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